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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,131	07/18/2008	Helen Francis-Lang	05-1037-A5 (EX04-072C-US)	4871

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,131	FRANCIS-LANG ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4,5,7,11-15 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,8-10,16 and 17* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed December 7, 2010 in response to the Office Action of July 7, 2010, is acknowledged and has been entered. Claims 1-25 are pending. Claims 1, 2, 8, 10, 16, and 17 are amended. Claims 4, 5, 7, 11-15, and 18-25 remain withdrawn. Claims 1-3, 6, 8-10, 16, and 17 are currently being examined.

Claim Objections

2. Claim 3 is free of the art but is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 3 requires that the ells of the assay system have defective beta catenin function. It is noted that Bahmanyar et al (J of Cell Science, 2010, 123:3125-3135) determined that absence of functional beta catenin in cells had no effect on PLK4 function. PLK4 is required for the templated formation of centrioles and is a major regulator of centriole duplication.

New Rejections

(necessitated by amendments)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites "**(f) measuring the beta catenin pathway**" as an active step of the method. It is unclear exactly what is measured and what step is conducted in part (f) of claim 16, therefore the metes and the bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,976,893, Dennis et al, issued November 1999.

The claims have been amended to require PLK4 and detecting activity or expression of PLK4 in the assay system.

Dennis et al teach providing tumor cells comprising SAK (also known as PLK4) nucleic acid/protein, contacting the tumor cells with a SAK antisense nucleic acid, and determining a decrease in cell proliferation in the presence of SAK antisense as

compared to the absence of SAK antisense, hence an activity of SAK was determined in a cell proliferation assay in the presence or absence of SAK antisense (Example 4; col. 17, line 44 to 65; col. 18, lines 43-67). Dennis et al further teach determining expression levels or kinase activity of SAK in the presence or absence of test agents (col. 4, line 59 to col. 5, line 34; col. 17, line 44 to col. 18, line 67; claims 1-4). Given the method of Dennis et al comprises the same method steps as instantly claimed, the method of Dennis et al would necessarily identify a candidate beta catenin pathway modulating agent.

5. Claims 1, 2, 6, 8, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 7,413,870, Hitoshi et al, filed December 2001.

Hitoshi et al teach methods of identifying modulators of SAK (also known as PLK4) comprising providing an assay system or cellular assay system comprising SAK nucleic acid; contacting the assay system with test agents including antisense SAK, and measuring the expression or activity of SAK, or cellular proliferation in the presence or absence of the test agent (abstract; col. 1, lines 59 to col. 2, line 58; col. 3, lines 4-6; col. 4, lines 62 to col. 5, line 22; col. 7, lines 15-37; col. 14, lines 36 to col. 15, line 19; col. 20, lines 30 to col. 27, line 25; Example 1 and 2; Figures 12-13; claims 1-9). Given the method of Hitoshi et al comprises the same method steps as instantly claimed, the method of Hitoshi et al would necessarily identify a candidate beta catenin pathway modulating agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,976,893, Dennis et al, issued November 1999 or US Patent 7,413,870, Hitoshi et al, filed December 2001 in view of Hudziak et al (Antisense & Nucleic Acid Drug Development, 2000, 10:163-176, IDS).

Dennis et al teach providing tumor cells comprising SAK (also known as PLK4) nucleic acid/protein, contacting the tumor cells with a SAK antisense nucleic acid, and determining a decrease in cell proliferation in the presence of SAK antisense as compared to the absence of SAK antisense, hence an activity of SAK was determined in a cell proliferation assay in the presence or absence of SAK antisense, as set forth above. Dennis et al further teach screening test agents to find potential therapeutic agents for cell proliferative disorders (col. 4, line 59 to col. 5, line 34; col. 17, lines 44-54).

Hitoshi et al teach methods of identifying modulators of SAK (also known as PLK4) comprising providing an assay system or cellular assay system comprising SAK nucleic acid; contacting the assay system with test agents including antisense SAK, and measuring the expression or activity of SAK, or cellular proliferation in the presence or absence of the test agent, as set forth above. Hitoshi et al teach screening test agents

to find potential therapeutic agents for cancer treatment (abstract; col. 1, lines 35-55; col. 2, lines 1-6).

Dennis et al and Hitoshi et al do not teach that the SAK antisense test agent is a phosphothioate morpholino oligomer (PMO).

Hudziak et al teach that PMOs are a known class of antisense agents that can be used in cell proliferation inhibition assays and PMOs have many properties considered desirable for antisense agents (abstract; p. 163, col. 1-2; Figure 8).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to and one would have been motivated to use PMOs as antisense agents in the methods of either Dennis et al or Hitoshi et al given Hudziak teach PMOs are known, successfully used in cell proliferation assays, and have many properties considered desirable for use as antisense agents. One of ordinary skill in the art would have a reasonable expectation of success using PMOs in the method of either Dennis et al or Hitoshi et al given PMO technology, function, and structure were known and successfully used in cell proliferation assays.

Finally, the Supreme Court has determined, in *KSR International Co. v. Teleflex, Inc.*, 550 U.S._, 82, USPQ2d 1385 (2007), that ".....[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" (KSR, 550 U.S. at_, 82 USPQ2d at 1395). The court further found that "..... the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious" (KSR,

550 U.S. at_, 82 USPQ2d at 1395-1396). Thus, when considering obviousness of a combination of known elements, the operative question is "whether the improvement is more than the predictable use of prior art elements according to their established functions" ((KSR, 550 U.S. at_, 82 USPQ2d at 1396).

Given the above, applying the same logic to the instant process claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the antisense oligo of Dennis et al or Hitoshi et al for the PMO of Hudziak et al, to assay cell proliferation because the prior art method of Dennis et al or Hitoshi et al differs from the claimed method only by the substitution of the known PMO antisense technology as claimed. Given that both antisense technology and PMO antisense technology were conventional and well known in the art at the time the invention was made wherein their functions were well known in the art, substitution of PMO for the antisense into the method of Dennis et al or Hitoshi et al would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The claims are obvious over the cited references because the results yielded would be no more than one would expect from such a substitution.

7. All other rejections recited in the Office Action mailed July 7, 2010 are hereby withdrawn in view of amendments.

8. **Conclusion:** Claim 3 is objected to. Claims 1, 2, 6, 8-10, 16, and 17 are rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LAURA B GODDARD/
Primary Examiner, Art Unit 1642